# 510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K060686

## 1. Submitter's Identification:

JUN - 9 2006

Microlife Intellectual Property GmbH, Switzerland

Max Schmidheiny-Strasse 201
9435 Heerbrugg / Switzerland

Date Summary Prepared: January 11, 2006

## 2. Name of the Device:

Microlife Automatic Blood Pressure Monitor, Model BP3AC1-1 PC.

## 3. Information for the 510(k) Cleared Device (Predicate Device):

Microlife Automatic Blood Pressure Monitor, Model BP3BT0-AP, K#041411.

## 4. Device Description:

Microlife Automatic Blood Pressure Monitor, Model BP3AC1-1 PC, is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive **MAM (Microlife Average Mode)** technique in which an inflatable cuff is wrapped around the Upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

The device detects the appearance of irregular heartbeat during measurement, and the arrhythmia symbol " "is displayed after the measurement. In additional, the device can be used in connection with your personal computer **(PC)** running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

## 5. Intended Use:

The Microlife Automatic Blood Pressure Monitor, Model BP 3AC1-1 PC, is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive **MAM (Microlife Average Mode)** technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

## 6. Comparison to the 510(k) Cleared Device (Predicate Device):

Both devices use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. An upper arm cuff is inflated automatically; deflate rate is controlled by a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units. Moreover, both devices have irregular heart beat detection function.

The differences between BP3AC1-1 PC and the predicate device are described as the following:

### 1.1. Average Mode function (MAM function):

BP3AC1-1 PC contains a switchable average mode in which the device automatically repeats 3 individual measurements cycles. After that, the average of these 3 individual measurements is calculated and also be shown on the display.

### 1.2. PC-link function:

BP3AC1-1 PC can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the blood pressure monitor to personal computer via USB cable. All the memory data can be transferred to the connected computer through USB cable and be shown on the computer

monitor. After transferred to computer, the memory data can then be saved in the personal computer memory.

## 7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Automatic Blood Pressure Monitor, Model BP3AC1-1 PC in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following tests were conducted accordingly:

a. Reliability Test - Storage test
b. Reliability Test - Operation test
c. Reliability Test - Vibration test
d. Reliability Test - Drop test
e. Reliability Test - Life test
f. EMC Test
g. PC-link software BPA version 3.1.6 test report

None of the tests demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It is then concluded that the Microlife Automatic Blood Pressure Monitor, Model BP3AC1-1 PC, meets all relevant requirements of the aforementioned tests.

## 8. Discussion of Clinical Tests Performed:

Clinical performance of the modified device will remain unchanged; therefore anther clinical test for the modified device, BP3AC1-1PC is not required.

## 9. Conclusions:

We have demonstrated that the Microlife Automatic Blood Pressure Monitor, Model BP3AC1-1 PC, is as safe and effective as the predicate device, the Microlife Automatic Blood Pressure Monitor, Model BP 3BT0-AP based on electrical,

mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and, the ANSI/AAMI Voluntary Standard, SP10-2002 testing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2006

Microlife Intellectual Property
c/o Mr. Tzu-Wei Li
Center for Measurement Standards/
Industrial Technology Research Institute
Bldg 16, 321 Kuang Fu Rd. Sec. 2
Hsinchu, Taiwan 30042 R.O.C.
R.O.C.

Re: K060686
Trade/ Name: Microlife Automatic Blood Pressure Monitor, Mode BP3AC1-PC
Regulation Number: 21 CFR 870.1130
Regulation Name: Blood Pressure Measurement System, Non-invasive
Regulatory Class: II (two)
Product Code: DXN
Dated: March 6 and May 17, 2006
Received: March 15 and May 23, 2006

Dear Mr. Li:

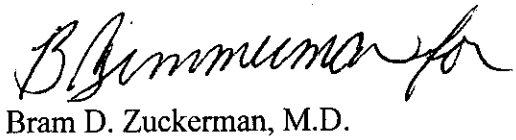
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Form



510(k) Number (if known):_____

Device Name: Microlife Automatic Blood Pressure Monitor , Model BP3AC1-1PC

Indications for Use:

The Microlife Automatic Blood Pressure Monitor, Model BP 3AC1-1 PC is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive MAM (Microlife Average Mode) technique in which an inflatable cuff is wrapped around the upper arm.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

| Prescription Use _____ | AND/ | Over-The-Counter Use __X__ |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | OR | (21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B Cummings

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060686